REMARKS/ARGUMENTS

Reconsideration of the present application is respectfully requested. With this amendment, claims 1-6, 8-22 and 30 are pending.

Claims 1, 2, 5, 6, 14, 22, and 30 have been amended. Support for the amendments is found in the claims as originally filed and on page 17, line 26, of the specification. No new matter has been added by way of the amendments.

Claims 7 and 23-29 are cancelled as being drawn to non-elected inventions. Applicants reserve the right to pursue these claims in a continuation or divisional application or to take other such appropriate action to seek protection of this cancelled subject matter.

Specification

The specification is objected to for the following formalities: "The specification refers to the data in Table 5 on page 77, lines 5-6 of the specification, however there is no Table 5 in the specification. Appropriate correction is required."

The specification has been amended to remove the reference to "Table 5".

Claim Objections

Claims 1, 6, 14, and 22 are objected to as reciting non-elected subject matter.

Claims 1, 6, 14, and 22 have been amended to remove the non-elected subject matter.

Claim Rejections - 35 USC §112

Written Description

Claims 1-6, 8-22, and 30 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Claims 1, 2, 5, 6, 14, 22, and 30 have been amended to further prosecution. This rejection is respectfully traversed with respect to the claims as amended.

The Office Action states: "Applicants describe SEQ ID NO: 1 comprising a polynucleotide sequence that encodes SEQ ID NO: 2 a beta 1, 4-mannan synthase.

Applicants do not describe any other mannan synthases that have at least 80% sequence identity to SEQ ID NO:1 or hybridize to SEQ ID NO:1 or comprise a fragment of SEQ ID NO:1 and possess mannan synthase activity."

The Office Action asserts: "…Applicants fail to describe structural features common to members of the claimed genus of mannan synthases that are encoded by the polynucleotides that hybridize to SEQ ID NO:1 or have at least 80% sequence identity to SEQ ID NO:1. …given the lack of description of the necessary elements essential for mannan synthase activity, it remains unclear what features identify a mannan synthase. Since the genus of mannan synthases has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath [sic] of the claims."

The Examiner's attention is respectfully directed to the recent Federal Circuit decision *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). In *Falkner*, Circuit Judge Gajarsa held that "there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." 448 F.3d at 1366. This decision reinforces Applicants' ability to fulfill the written description requirement by providing a specification which will be interpreted in light of the high level of skill in the art of plant genetics. Moreover, *Falkner* articulates what is *not* required for fulfilling the written description requirement (i.e., examples are not necessary, reduction to practice is not required, and recitation of known structure is not required). Id. As such, the Examiner's requirement for a recitation of structure appears to have gone astray from recent case law.

The "Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, ¶ 1, 'Written Description' Requirement" state that a genus may be described by "sufficient description of a representative number of species … or by disclosure of

relevant, identifying characteristics , *i.e.* structure or other physical and/or chemical properties." *Id.* at 1106. This is in accordance with the standard for written description set forth in *Regents of the University of California v. Eli Lilly & Co*, 119 F.3d 1559 (Fed. Cir. 1997), which the Examiner cites, where the court held that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, or chemical name' of the claimed subject matter sufficient to distinguish it from other materials." 119 F.3d at 1568, citing *Fiers v. Revel* 984 F.2d 1164 (Fed. Cir. 1993).

The amended claims of the present application meet the requirements for written description set forth by the Federal Circuit and the MPEP. First, the amended claims have been limited to a specific mannan synthase sequence (SEQ ID NOs: 1 and 2) and variants and fragments thereof. The variants and fragments encompassed by the amended claims recite polynucleotide sequences having a specified percent identity (i.e., 90%) to that polynucleotide sequence that encodes a polypeptide having mannan synthase activity. Methods for determining percent identity between any two sequences and for preparing fragments are known in the art and are provided in the specification. See the specification beginning on page 24, line 27.

The Examiner is also reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2000). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2000). Here, Applicants have identified and disclosed conserved regions and motifs described on page 10, line 25; Examples 5 and 6 beginning on page 54; and in Figures 9 and 10. Further, a model for a functional minimal mannan

synthase based on the predicted transmembrane domains is described in Example 9 beginning on page 55 and in Figure 13. A fragment of the mannan synthase polypeptide used to raise specific antibodies is described in Example 17, on page 72. The recitation of these structures and fragments is believed to be sufficient to satisfy the written description requirement.

The Office Action further states: "Sequences that hybridize with SEQ ID NO:1 under conditions of unspecified stringency and which are 80% complementary to SEQ ID NO:1 encompass naturally occurring allelic variants, mutants of SEQ ID NO:1, as well as sequences encoding proteins having no known mannan synthase activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotide sequences encompassed by the hybridization language or percent identity language as set forth in the claims."

Although Applicants maintain that the claims as originally submitted demonstrate possession of the claimed invention, claims 1, 6, and 14 (and all claims dependent thereon) have been amended to expedite prosecution.

Specifically, the claims recite that the claimed polynucleotide sequences encode a polypeptide (or variant or fragment thereof) that has mannan synthase activity. Mannan synthase activity is described in the application in terms of enzyme kinetics in Example 1, page 50, lines 4-16. The specification and the art further provide standard assays that may be used to measure and assess mannan synthase activity. See Example 2. Therefore, both the structural and functional properties that characterize the genus of sequences that can be used to practice the invention are specifically recited in the claims. Sequences within the scope of the claims can readily be identified by the methods set forth in the specification.

In order to satisfy the written description requirement of 35 U.S.C. § 112, the application must reasonably convey to one skilled in the art that the applicant was in possession of the claimed subject matter at the time the application was filed. *Vas-*

Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). Every species encompassed by the claimed invention, however, need not be disclosed in the specification to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988). The Federal Circuit has made it clear that sufficient written description requires simply the knowledge and level of skill in the art to permit one of skill to immediately envision the product claimed from the disclosure. *Purdue Pharm L.P. v. Faulding In.*, 230 F.3d 1320 1323, 596 USPQ2d 1481, 1483 (Fed. Cir. 2000) ("One skilled in the art must immediately discern the limitations at issue in the claims.").

In summary, it is submitted the specification provides an adequate written description of the claimed invention. In particular, the specification and art provide: polynucleotide and amino acid sequences for mannan synthase proteins; guidance regarding sequence alterations that do not disrupt biological activity of a protein; guidance for determining percent identity of sequences; mutagenesis and molecular biology techniques for producing fragment and variant sequences; methods for assaying mannan synthase activity; and methods for transforming plants with a DNA construct of interest.

Accordingly, Applicants respectfully submit that in view of the present disclosure, the above remarks, and the knowledge and level of skill in the art the skilled artisan would readily envision the claimed invention in light of the specification.

Enablement

Claims 1-6, 8-22 and 30 are rejected under 35 USC §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make or use the invention. Claims 1, 2, 5, 6, 14,

22, and 30 have been amended to further prosecution. This rejection is respectfully traversed with respect to the claims as amended.

The Office Action states: "The claims are broadly drawn to a nucleotide sequence having at least 80% identity to SEQ ID NO:1, nucleotide sequence that hybridize to SEQ ID NO:1 under conditions of unspecified stringency; and fragments of SEQ ID NO:1 that encode a mannan synthase; and a method of altering galactomannan and a method of producing gum in a plant transformed therewith; and plants and plant cells thereof. ...Applicants do not teach any other polynucleotides encoding a mannan synthase sequence other than SEQ ID NO:1 encoding SEQ ID NO:2."

The Examiner appears to be suggesting that in order to satisfy the enablement requirement Applicants must demonstrate that every polynucleotide that encodes a polypeptide, or fragment thereof, exhibiting mannan synthase activity could be used to successfully practice the invention such that no experimentation would be required. According to the applicable case law, however, the test of enablement is not whether experimentation is necessary to make and use an invention, but rather if experimentation is necessary, whether it is undue. *In re Angstadt*, 198 USPQ 214, 219 (C.C.P.A. 1976). Furthermore, a considerable amount of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

In order to identify the polynucleotide sequences (and the polypeptides they encode) encompassed by the present claims, one of skill in the art would only need to prepare variants and fragments of a polypeptide of claim 1 having the specified characteristics recited in the claims (e.g., 90% sequence identity and having mannan synthase activity) and then assay these polypeptides for mannan synthase activity. Routine methods for preparing variants and fragments and testing the resulting polypeptides for the desired activity are routine in the art and described in the

specification. Although some experimentation is required to practice the claimed invention, it is now customary in the art to generate a number of sequences and to test them for a desired function, and, therefore, such experimentation is not undue, particularly in view of the routine nature of the required methods. A person skilled in the art would only need to utilize standard molecular biology and mutagenesis techniques, routine plant transformation methods, and routine activity assays as described in working Example 1.

The Office Action asserts: "The state-of-the-art is such that one of skill in the art cannot predict whether putative processive beta glycosyl-transferases encode an enzyme that catalyzes galactomannan or some other hemicellulose product because the genes encoding this superfamily of enzymes may represent up to 1% of the total number of genes active in the genome of a plant … and although various approaches have been pursued, there are only a few examples of successful isolation and characterization of polynucleotides encoding polypeptides that synthesize noncellulosic polycaccharides of the plant cell wall … and that the state of the art for drawing distinctions between family members of processive beta glycosyl-transferases sufficient to identify specific activity is not well resolved." The Office Action cites three references to support this assertion.

Applicants respectfully disagree with the Examiner's conclusions. The citation of Saxena *et al.* fails to take into account the considerable advancement in the art of sequence analysis and comparison since it's publication in 2000. The specification provides a number of sequence alignments between the polypeptides that encode various members of these gene families and clearly points out domains conserved motifs diagnostic of mannan synthases (see Figs. 7-9). The Examiner cites Liepman *et al*. as stating that isolation and characterization of these genes has "proven difficult". Yet Liepman *et al*. cite a publication based on the present disclosure for doing so. (see Liepman *et al.* page 2221, col. 2). Dhugga *et al*. states: "Mannans are present in the walls of a wide variety of plant cells (3). The [mannan synthase]

protein is *fairly divergent* from it's nearest homolog...." (italics added, see Dhugga *et al*. page 365, col. 3).

Accordingly, the three references fail to demonstrate that isolating and characterizing the polypeptides of the claimed invention place a burden of undue experimentation on the skilled artisan.

The Office Action concludes: "Given the lack of guidance in the instant specification, the limited number of working examples and the unpredictability in the art, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate sequences similar to a multitude of processive beta glycosyltransferases and test for mannan synthase activity by transforming a myriad of plants and analyzing for increases in expression patterns and product formation across any number of plant species to determine the identity of a putative beta-glycosyltransferase encoding polynucleotide."

The Examiner's rejection with respect to the isolation of a "multitude of processive beta glycosyltransferases" has been obviated by the limitation of the claims to polynucleotides that encode specific polypeptides of interest (e.g. SEQ ID NO:2). The claims have also been amended to recite variants of the claimed polypeptides, wherein the variant comprises at least 90% sequence identity to a nucleotide encoding the polypeptide and having mannan synthase activity. Support for this claim amendment can be found on page 17. The necessary molecular biology and mutagenesis techniques for preparing the fragments and variants of the invention are *routine* and described in the specification. See, for example, pages 18-19. Moreover, a working example for assaying the expressed polypeptides for mannan synthase activity is described in Example 1.

The Federal Circuit has held "[t]he enablement requirement is met if the description enables *any* mode of making and using the claimed invention." *Engel Industries Inc. v. The Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) (emphasis added). Applicants' specification clearly meets the enablement standard

set forth in *Engel* with regard to the pending claims because the specification provides sufficient guidance to enable one of skill in the art to identify and make the mannan synthase polynucleotides encompassed by the claims, to produce transformed plants comprising these sequences, and to analyze plants expressing the mannan synthase polynucleotides.

In light of the above arguments, the level of skill and knowledge in the art, the presence of working examples, and the guidance provided in the specification, Applicants respectfully submit that the specification is enabling for the full scope of claims 1-6, 8-22, and 30. Thus, the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement should be withdrawn.

CONCLUSION

The Examiner is respectfully requested to withdraw the rejection of the claims. In view of the above remarks and claim amendments, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

Respectfully submitted,

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